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| SERIAL NUMBER | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|---------------|-------------|----------------------|---------------------|
| 07/599,543    | 10/18/90    | OPPERMANN            | H CRP-056           |

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| EXAMINER<br>NUTTER, N |
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| ART UNIT<br>1503 | PAPER NUMBER<br>17 |
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DATE MAILED: 02/26/92

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined: ☐ Responsive to communication filed on \_\_\_\_\_: ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), \_\_\_\_\_ days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- |   |   |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892.        | 2. <input checked="" type="checkbox"/> Notice re Patent Drawing, PTO-948.       |
| 3. <input checked="" type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449.  | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152 |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____   |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-23 are pending in the application.  
Of the above, claims 3-7, 11-16, 19, 20 and 23 are withdrawn from consideration.
2. ☐ Claims \_\_\_\_\_ have been cancelled.
3. ☐ Claims \_\_\_\_\_ are allowed.
4. ☒ Claims 1, 2, 8-10, 17, 18, 21 and 22 are rejected.
5. ☐ Claims \_\_\_\_\_ are objected to.
6. ☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed \_\_\_\_\_, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other \_\_\_\_\_

EXAMINER'S ACTION

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-21 and 23 , drawn to osteogenic polypeptides, classified in Class 530, subclass 350 plus.

II. Claim 22, drawn to a DNA sequence, classified in Class 536, subclass 18.7 plus.

The inventions are distinct, each from the other because of the following reasons:

The inventions as disclosed are related but are distinct as claimed. They are drawn to products, not disclosed as capable of use together, have different functions and effects. The polypeptides can be made by a materially different process, as from being derived by DNA, such as by solid phase peptide synthesis.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and as shown by their different classification restriction for examination purposes as indicated is proper.

If applicants elect the invention of the Group I claims, the following requirement is placed in effect. This application contains claims directed to the following patentably distinct species of the claimed invention:

- (1) MOP-2, claims 2 and 8-10,

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- (2) hOP-2, claims 3 and 11,
- (3) Sequence ID No. 7, claim 4,
- (4) Sequence ID No. 8, claim 5,
- (5) Sequence ID No. 5, claims 6 and 7,
- (6) Sequence ID No. 9, claims 12,
- (7) Sequence ID No. 10, claim 13,
- (8) Sequence ID No. 11, claim 14,
- (9) Sequence ID No. 2, claim 15, and
- (10) Sequence ID No. 4, claim 16

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Currently, 1, 17, 18 and 21 are generic.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or

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admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

It is noted that claims 19 and 20 are improper in that "host cell" has no antecedent basis in claim 15 from which they depend. Otherwise, the claims, if dependent from claim 18 would be generic claims.

During a telephone conversation with Edmund R. Pitcher on 18 February 1992 a provisional election was made with traverse to prosecute the invention of Group I, and the species embodied as mOP-2, Sequence ID No.1, claim 2 and 8-10. Affirmation of this election must be made by applicant in responding to this Office action.

Claims 3-7, 11-16, 19, 20 and 23 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

Claims 1, 8-10, 17, 18 and 21 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims do not give any identifying characteristics such as molecular weight, pKa or other variables which would serve to "fingerprint" the polypeptides to some exactness which would be in conformity with 35 USC 112, second paragraph.

Claims 1, 8-10, 17, 18 and 21 are rejected under the judicially created doctrine of obviousness-type double patenting

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as being unpatentable over claims 1-8 and 10 of U.S. Patent No. 600,024. Although the conflicting claims are not identical, they are not patentably distinct from each other because the manipulation of various amino acids which are not necessary for osteogenic activity, due to the broader number of identical amino acids would have been within the skill of the art at the time the invention was made.

The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. In re Vogel, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.78(d).

Claims 1, 8-10, 17, 18 and 21 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 and 21 of copending application Serial No. 810,560. Although the conflicting claims are not identical, they are not patentably distinct from each other because the manipulation of various amino acids would have been within the skill of the art for the result of osteogenic activity.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented

N. Nutter/mbb  
February 23, 1992

A handwritten signature in cursive script that reads "Nathan M. Nutter".

**NATHAN M. NUTTER  
PATENT EXAMINER  
ART UNIT 153**